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10/003,996

11/15/2001

Peter M. Bonutti

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21355 EAST DIXIE HIGHWAY  
SUITE 115  
MIAMI, FL 33180

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

02/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/003,996

Applicant(s)

BONUTTI, PETER M.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01/30/2004, 11/30/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-44, 46, 47, 49, 51-60 and 69-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-44, 46, 47, 49, 51, 57-60 and 69-76 is/are allowed.
- 6) ☒ Claim(s) 52-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

It is noted that full faith and credit is being given to the action by the previous Examiner in accordance with MPEP 706.04.

### ***Election/Restrictions***

Upon further consideration and review of Applicant's response, the election/restriction requirement is withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary (U.S. Patent No. 5,073,373) in view of Kambin (U.S. Patent No. 4,573,448).

O'Leary discloses the claimed invention except for the first tubular member used to cut the tissue from the first location. Kambin teaches a tissue-cutting instrument that provides a rotatable cutter and suction (Column 3 lines 47-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the cutter of Kambin since Kambin's cutter is used

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to remove tissue fragments, which can be modified in the method of O'Leary which cuts and removes tissue fragments in order to make the desired bone paste.

Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary ' 373 in view of Kambin '448 as applied above, and further in view of Muller-Lierheim (U.S. Patent No. 4,828,563) and Amrani (U.S. Patent No. 4,210,580).

O'Leary, as modified, discloses the closed invention except for centrifuging the blood or body tissue to separate one or more components from the blood. Muller-Leirheim teaches that growth factors, particularly fibronectin, are added to bone implants to enhance biocompatibility and mechanical strength (Column 1 line 37-Column 2 line 7). Amrani teaches that fibronectin may be obtained from blood plasma by centrifuging the blood plasma (Column 2 lines 26-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the additional step of centrifuging blood to obtain fibronectin, an additive to an implant material, to enhance the biocompatibility and strength of the O'Leary implant material.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary '373 in view of Kambin '448 as applied above, and further in view of Bagby '848.

O'Leary, as modified, discloses the claimed invention except for the removal of tissue from the second location. Bagby teaches that diseased tissue must be removed before an implant is inserted into the body (Column 4 lines 54-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary, as modified, with the step of removing tissue from the

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second location in order to remove diseased or damaged tissue before the implant was inserted.

### ***Response to Arguments***

Applicant's arguments filed 01/30/2004 have been fully considered but they are not persuasive.

In response to Applicant's argument that the cited references do not include certain features of Applicant's invention, the limitations on which the Applicant relies (i.e., that the tissue packed or compressed into a plug of tissue graft, a flexible drill shaft, and the tissue contains blood) are not stated in the claims that are currently being rejected. Therefore, it is irrelevant whether the reference includes those features or not.

Applicant argues that the O'Leary reference discloses using allogenic bone rather than autogenic bone. However, upon review of the specification, the O'Leary reference states that allogenic is "preferred." Moreover, in column 1, lines 19-24, the reference discusses similar bone harvesting procedures that have been performed in dogs using autogenic bone (see the reference to the Habal et al. article). Therefore, the examiner respectfully disagrees that the O'Leary reference cannot be used in the 103(a) rejection because it does not teach or suggest using autogenic bone, since clearly the reference mentions the use of autogenic bone, and furthermore, it was well known in the art at the time of the invention that autogenic, allogenic, and xenogenic are the three donor sources of tissue and can be used interchangeably depending on the situation.

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Applicant further argues that the Kambin reference does not remedy the deficiencies of O'Leary because the tissue-harvesting tool is used for intervertebral tissue rather than bone tissue. The examiner respectfully disagrees that the cutting tool of the Kambin reference cannot be combined and/or modified by one of ordinary skill in the art to remove the bone tissue of the O'Leary reference. Clearly the bone fragments of the O'Leary reference must be removed from a donor via some method of tissue removal; however, O'Leary is silent as to how the bone tissue is removed. Kambin provides a tissue cutter and method of tissue removal that remedies the deficiencies of the O'Leary reference. Although the Kambin reference discloses removing disc tissue, it would be capable of cutting other tissue such as bone, and the methods disclosed by Kambin could obviously be modified to remove tissue from other areas of the body. Applicant is reminded that the test for obviousness is not whether the features/method may be bodily incorporated into the other to produce the claimed subject matter, but simply what combination of references makes obvious to one of ordinary skill in the pertinent art.

Applicant also argues that neither O'Leary, Kambin, nor Bagby discloses removing tissue from a second location, and therefore the 103(a) rejection that combines those references is not proper since it does not anticipate all of the claimed invention. The examiner respectfully disagrees. While the O'Leary reference is silent as to how the bone fragments are removed, it is inherent that the bone fragments must be removed in order to process the bone fragments in the manner described in the O'Leary specification (e.g. pulverization). The O'Leary reference can be combined with

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the Kambin reference to meet the specifics of the claimed method step of removing tissue from a first location and moving it outside the body. The Bagby reference teaches that bone can be removed from a location in order to make space for the implantation of a bone graft materials. By combining the Bagby reference with the O'Leary and Kambin combination, one is able to arrive at all the claimed limitations: first, removal of the tissue from a first location (Kambin), second, processing of the tissue to make a bone material and implantation of the bone material into another area of the body (O'Leary), and third, the implantation is performed after removing tissue from the second location, or area of implantation (Bagby).

The rejections are deemed proper.

#### ***Allowable Subject Matter***

Claims 36-44, 46, 47, 49, 51, 57-60 and 69-76 are allowed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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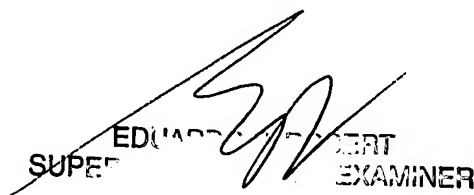
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



SUPERVISOR  
EDUARDO C. ROBERT  
EXAMINER